

Statement



Opposing Wisconsin Assembly Bill 12 Which Bans Gifts to Practitioners from Pharmaceutical Manufacturers

March 13, 2007

Position: PhRMA respectfully opposes Wisconsin's AB 12 regarding a ban on gifts to health care practitioners from pharmaceutical manufacturers because it may jeopardize the quality of health care that Wisconsin receive.

PhRMA respectfully opposes AB 12 because it would ban, with limited exception, all gifts to health care practitioners from pharmaceutical manufacturers. The limited exceptions would allow samples to be given to practitioners as well as gifts given to family members. The bill establishes a \$10,000 fine for violating the ban.

Given that the pharmaceutical industry has issued its own voluntary guidelines related to communications with health care practitioners, this legislation is duplicative. Companies are striving to adhere to the letter and the spirit of their guidelines. In addition, the U.S. Department of Health and Human Services, Office of Inspector General recently issued a guidance regarding similar communications that places stricter rules on manufacturers. It is unnecessary and duplicative for the states to regulate this type of activity when the federal government is doing so and the industry is voluntarily adhering to its own code.

In the complex pharmaceutical and health care marketplace, when a state limits certain actions with such a broad prohibition, it can unintentionally prohibit many legitimate activities that could be designed to improve health care quality. Often manufacturers provide educational programs and materials, including reference books. Additionally, prescription medicine manufacturers may provide honoraria to physicians speaking at educational events that are attended by their colleagues. This honoraria helps attract experts in the field that can educate medical practitioners on the latest developments in the treatment of diseases. Without these experts, the quality of continuing educational events may be seriously diminished. Many times these seminars, conferences, and meetings are the only opportunities practitioners have to attend continuing education throughout the year. Manufacturers can also offer medical students, residents, or fellows scholarships to attend these conferences. AB 12's proposed ban could jeopardize opportunities, diminishing health care practitioner training opportunities in the Wisconsin and having a harmful impact on the health care of Wisconsin patients.

Manufacturer relationships with health care professionals are meant to benefit patients and to enhance the practice of medicine. Interactions are focused on informing health care professionals about products, providing scientific and educational information, and supporting medical research and education. Pharmaceutical marketing serves the following positive purposes for physicians: enables physicians to learn quickly and accurately about new therapies and diagnostic tools; provides FDA-regulated information that must be impartial and disclose all risks; provides a mechanism for physicians to receive prompt answers to questions about medical research and the proper use of drugs; and, provides exposure to some leading authorities in physicians' fields through continuing medical education and other programs.

For these reasons, PhRMA respectfully requests Wisconsin legislators oppose AB 12 because it could jeopardize health care for Wisconsin patients.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading research-based pharmaceutical and biotechnology companies, which are devoted to developing medicines that allow patients in the United States and around the world to live longer, healthier, and more productive lives. In 2004, PhRMA's member companies brought thirty-eight new prescription drugs and biologics to market, including medicines for diseases that affect millions of patients, such as, Parkinson's disease, cancer, kidney disease, diabetes, and heart disease. Additionally, PhRMA member companies invested an estimated \$49 billion in 2006 in discovering and developing new medicines that help combat diseases that threaten the well-being of Americans and help reduce the economic loss caused by an ailing workforce.

Pharmaceutical Research and Manufacturers of America

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THOMAS E. MOORE

GOVERNMENT AFFAIRS

March 20, 2007

To: Representative Leah Vukmir
Members, Assembly Committee on Health
From: Tom Moore
RE: **Pharmaceutical Research and Manufacturers of America testimony
regarding Assembly Bill 12**

I would like to explain PhRMA's position on this bill and why we oppose the measure in general terms and then I would like to make some specific comments about the draft.

I am sure it will come as no surprise that PhRMA opposes this bill, but I would ask you not to confuse our position with a lack of concern about ethical practices within the industry.

Just about five years ago I testified before this committee on an identical bill authored by Representative Schneider. At that time I referenced the ongoing work within PhRMA to revise and expand rules which had been in place relating to the receipt of gifts developed by the American Medical Association Council on Ethical and Judicial Affairs.

In August of 2002, PhRMA completed work on the PhRMA Code on Interactions with Healthcare Professionals. Since its release in 2002, the PhRMA Code has been widely adopted by researched based pharmaceutical manufacturers to govern their companies' relationships with physicians and other healthcare professionals.

Guidelines in the Code make it clear that interactions between sales representatives and healthcare professions must focus on informing the physician or other professional about scientific information supporting medical research and educational information which will maximize patient's benefits. Interactions should not include entertainment. They should occur at a venue conducive to providing scientific or educational information. This means no "dine and dash", no entertainment and no recreational or sporting events.

The Code allows educational and practice-related items to be provided to healthcare professionals (like anatomical models but not, say golf bags) but must be for the benefit of patients and of less than substantial value (\$100 or less). Items for the personal benefit of the healthcare professional should not be offered or distributed. In short, nothing should be offered or provided that would interfere with the independence of the physicians prescribing practices.

In April of 2003, the Department of Health and Human Services Office of Inspector General issued guidelines for pharmaceutical manufacturers to use in developing compliance programs. In their report, the OIG specifically named the PhRMA Code as a benchmark which could be used by manufacturers to help achieve compliance with applicable healthcare fraud and abuse statutes and regulation, stating that implementing the PhRMA Code "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with applicable federal health care program requirements."

I believe the voluntary efforts of America's researched based pharmaceutical manufacturers to devise and implement the PhRMA Code demonstrates a legitimate effort within the industry to address the issues involving the relationship between individuals marketing and those prescribing prescription drugs.

With respect to the provisions of Assembly Bill 12, I would suggest that it is overly restrictive, and it's penalties are extreme.

AB 12 would prohibit a representative of a drug manufacturer from giving anything of monetary value to a practitioner, except product samples. This bill would effectively shut down the delivery of educational material which is often provided for physicians and their patients by pharmaceutical manufacturers. Drug reps. provide anatomical models you see in your doctor's office, they provide medical textbooks and diagnostic equipment that benefits the patients. We would really be taking a step backward by simply banning anything of monetary value which would be donated to a physician's practice by a drug manufacturer.

Secondly, I think that a fine of up to \$10,000 per office is excessive. In fact, it equals the highest forfeiture allowed under Chapter 450. For example, under that chapter dispensing drugs at an unlicensed facility will get you a fine of at least \$25 but not more than \$50 per offence. Practicing pharmacy while impaired by alcohol or drugs - that will get you a fine not to exceed \$1,000 per offence. Improper handling of a "highly toxic" substance can get you between \$100 and \$1,000. Under this bill, giving a physician a stethoscope or pen can get you a \$10,000 fine per offence. I think that relative to the other forfeitures in this chapter AB 12 is simply excessive.

I believe the development and implementation of the PhRMA Code, in consultation with the medical community, is a noteworthy example of industry responding to criticism and actually implementing real change. Today, I can tell you, PhRMA member companies have very strict policies governing the activities of their sales forces. Violations of these company policies result in discipline and terminations. I think the industry should be commended for implementing serious steps to avoid any impropriety or even the appearance of impropriety surrounding the detailing of prescription medicines.



Wisconsin Medical Society

Your Doctor. Your Health.

TO: Assembly Committee on Health and Health Care Reform
Representative Leah Vukmir, Chair

FROM: Mark Grapentine, JD – Senior Vice President, Government Relations
Jeremy Levin – Government Relations Specialist

DATE: March 20, 2007

RE: Assembly Bill 12 – Testimony for Information Only

On behalf of more than 11,500 members statewide, the Wisconsin Medical Society thanks you for this opportunity to provide information for Assembly Bill 12, related to gifts given or offered by prescription drug manufacturers and distributors to encourage practitioners to prescribe certain drugs.

The Wisconsin Medical Society supports reasonable restrictions on gifts and payments given or offered by the pharmaceutical industry to certain practitioners. The Society and the American Medical Association have policies on this topic:

Society Policy:

ETH - 004

Physicians Accepting Gifts from the Pharmaceutical Industry: The Wisconsin Medical Society (Society) supports the following policy on accepting gifts from the pharmaceutical industry:

The acceptance of gifts from pharmaceutical representatives can create the appearance of unethical conduct on the part of physicians; and the demand of gifts from physicians to guarantee access to the physicians creates the need for the pharmaceutical industry to provide such gifts; therefore, the Society adopts the following from the American Medical Association code of Medical Ethics to avoid the acceptance of inappropriate gifts:

- Any gifts accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. Accordingly, textbooks, modest meals and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted.
- The compassionate use of medical samples by physicians, when freely given by pharmaceutical sales representatives is ethical.
- Individual gifts of minimal value are permissible as long as the gifts are related to the physician's work (e.g., pens and notepads).
- Subsidies to underwrite the costs of continuing medical education conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Since the giving of a subsidy directly to a physician by a company's sales representative may create a relationship that could influence the use of the company's products, any subsidy should be accepted by the conference's sponsor, who, in turn, can use the money to reduce the conference registration fee. Payments to defray the costs of a conference should not be accepted directly from the company by physicians who are attending the conference.

- Subsidies from industry should not be accepted directly or indirectly to pay the costs of travel, lodging, or other personal expenses of the physicians who are attending the conferences or meetings, nor should subsidies be accepted to compensate for the physician's time. Subsidies for hospitality should not be accepted outside of modest meals or social events that are held as part of a conference or meeting. It is appropriate for faculty at conferences or meetings to accept reasonable honoraria and to accept reimbursement for reasonable travel, lodging and meal expenses. It is also appropriate for consultants who provide genuine services to receive reasonable compensation and to accept reimbursement for reasonable travel, lodging and meal expenses. Token consulting or advisory arrangements cannot be used to justify the compensation of physicians for their time or their travel, lodging and other out-of-pocket expenses.
- Scholarship or other special funds to permit medical students, residents and fellows to attend carefully selected educational conferences may be permissible as long as the selection of students, residents or fellows who will receive the funds is made by the academic or training institution.
- No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practices. In addition, when companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods and materials should belong to the organizers of the conferences or lectures.

Office Sign:

TO OUR PATIENTS

In keeping with high standards in the practice of medicine, and to foster an ethical working relationship with the pharmaceutical manufacturers and marketers, our office complies with the guidelines of the American Medical Association and the Wisconsin Medical Society limiting gifts to *physicians from the pharmaceutical industry*.

With the escalating costs of prescription drugs, it is understandable that some would believe limiting pharmaceutical gifts and payments could be helpful. The Society believes some of these gifts and payments are worthy and that physicians can ethically accept them – especially scholarships and gifts that serve a genuine educational function. For this reason, the Society believes any legislation aimed at curtailing certain gifts should be consistent with Society policy.

Thank you for your attention to this information. If you have any further questions or need additional information, please feel free to contact Mark Grapentine at markg@wismed.org or Jeremy Levin at jeremyl@wismed.org. Both can be reached at 608.442.3800.

WDA Testimony in Support of AB 12 Gifts Given or Offered by Drug Companies

**Dr. Fred Jaeger, WDA Past President
Assembly Health Committee Public Hearing
Tuesday, March 20, 2007 - 11:00 AM – GAR Hearing Room**

Good morning, Madame Chair and members of the Assembly Health Committee. My name is Dr. Fred Jaeger. I am a general dentist who practices right here in Madison and I recently served as president of the Wisconsin Dental Association (WDA).

I'm here today to recommend that AB 12 be amended to allow drug manufacturers and distributors to sponsor continuing education (CE) courses for health care practitioners, including (but not limited) to dentists. WDA is not suggesting that drug companies be allowed to pay for individual practitioners to attend CE meetings but we do believe that language should be added that would allow a more general corporate sponsorship of CE courses. Our support for this is generated by the fact that corporate sponsorship allows for CE to be obtained at a more reasonable cost, not only for dentists but also for dental staff.

As witnessed by our support of AB 153 regarding mandatory CE for dentists, the WDA believes that all dentists should obtain a minimal level of CE each year. Fortunately, many of the dentists in this state also believe strongly in exposing their dental staff to CE courses as well. By allowing corporate sponsorship of CE courses, it holds the cost of the course down so a dentist may have enough incentive to pay for several staff people to attend a CE course alongside the dentist. This further fosters the team-oriented delivery of dental care which ultimately benefits the patient. Unlike more direct gifts to a health care practitioner, general or broad corporate sponsorship of a CE course does not create the type of relationship between a practitioner and a drug manufacturer that is the target of this bill draft.

Thank you for your time and attention. I would be happy to take any questions you might have.

MISSION STATEMENT

***The Wisconsin Dental Association advances the interests of its members and the dental profession
by promoting professional excellence and quality oral health care for the public.***

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